

What is Claimed Is:

1. A pharmaceutical composition for oral delivery administration comprising a pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, comprises the (+) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, and the (-) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, each chiral compound enantiomer formulated separately, either as an immediate release (IR) formulation or as a controlled release (CR) formulation, and wherein when measured by the USP type II dissolution method, the *in vitro* dissolution rates for the CR formulation and the IR formulation are:

<u>Time (hours)</u>	<u>% CR Release</u>	<u>% IR Release</u>
0	0%	0%
0.3	0-60 %	20-100 %
0.5	0-65 %	20-100 %
1.0	5-70 %	25-100 %
2.0	5-75 %	25-100 %
4.0	10-80 %	30-100 %
6.0	10-100 %	30-100 %
8.0	20-100 %	40-100 %
10.0	25-100 %	45-100 %
12.0	25-100 %	45-100 %
18.0	35-100 %	50-100 %
24.0	35-100 %	50-100 %

2. The pharmaceutical composition of claim 1, wherein the composition is a bi-layered tablet.

3. The pharmaceutical composition of claim 1, wherein the composition is formulated to provide appropriate administration to a patient without the undesirable known side effects attributed to one or the other enantiomer.

4. The composition of claim 1, wherein the CR formulation further comprises **TIMERx™-N** and one chiral compound enantiomer such that a gum to drug ratio of between about 1:3 to 3:1, respectively, is established.

5. The composition of claim 1, wherein the CR formulation further comprises TIMERx™-O and one chiral compound enantiomer such that a gum to drug ratio of between about 1:3 to 3:1, respectively, is established.

6. The composition of claim 1, wherein the (+) chiral compound enantiomer and the (-) chiral compound enantiomer are present in the composition at different mass quantities.

7. The composition of claim 1, wherein the (+) chiral compound enantiomer and the (-) chiral compound enantiomer are present in the composition at a percent ratio selected from the following table:

(+) Enantiomer	(-) Enantiomer
2	1
3	1
4	1
5	1
10	1
1	2
1	3
1	4
1	5
1	10

*a*

8. The composition of claim 1, wherein about 90% of the (+) chiral compound enantiomer and about 90% of the (-) chiral compound enantiomer are released within about 12 hours of administration.

9. a pharmaceutical composition for oral delivery administration comprising a pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, comprises the (+) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, and the (-) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, each chiral compound enantiomer formulated separately, either as an immediate release (IR) formulation or as a controlled release (CR) formulation, and wherein when administered to a patient, the pharmaceutical composition

provides the following percent of maximum (+) and (-) chiral compound enantiomer plasma concentrations:

Time (hours)	(+) Enantiomer	(-) Enantiomer
0	0%	0%
0.3	0-60 %	0-100 %
0.5	0-65 %	0-100 %
1.0	5-70 %	25-100 %
2.0	5-75 %	25-100 %
4.0	10-80 %	30-100 %
6.0	20-100 %	30-100 %
8.0	20-100 %	20-100 %
10.0	20-100 %	20-100 %
12.0	10-100 %	0-90 %
18.0	0-80 %	0-80 %
24.0	0-80 %	0-80 %

10. A pharmaceutical composition for oral delivery administration comprising a pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutically efficacious chiral compound, or a pharmaceutically acceptable salt thereof, comprises the (+) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, and the (-) chiral compound enantiomer, or a pharmaceutically acceptable salt thereof, each chiral compound enantiomer formulated separately, either as an immediate release (IR) formulation or as a controlled release (CR) formulation, wherein when administered to a patient, the pharmaceutical composition provides the following percent of maximum (+) and (-) chiral drug enantiomer plasma concentrations:

Time (hours)	(+) Enantiomer	(-) Enantiomer
0	0%	0%
0.3	0-40 %	0-100 %
0.5	0-45 %	0-100 %
1.0	5-50 %	25-100 %
2.0	5-55 %	25-100 %
4.0	10-80 %	30-100 %
6.0	20-100 %	30-100 %
8.0	20-100 %	20-100 %
10.0	10-100 %	20-100 %
12.0	0-80 %	10-90 %
18.0	0-80 %	0-80 %
24.0	0-80 %	0-80 %

- 47

Time (hours)	% (+) Tramadol Enantiomer Release	% (-) Tramadol Enantiomer Release
0	0%	0%
0.3	0-60 %	20-100 %
0.5	0-65 %	20-100 %
1.0	5-70 %	25-100 %
2.0	5-75 %	25-100 %
4.0	10-80 %	30-100 %
6.0	10-100 %	30-100 %
8.0	20-100 %	40-100 %
10.0	25-100 %	45-100 %
12.0	25-100 %	45-100 %
18.0	35-100 %	50-100 %
24.0	35-100 %	50-100 %

12. The pharmaceutical composition of claim 11, wherein the composition is a bi-layered tablet for oral delivery.
13. The pharmaceutical composition of claim 11, wherein the composition is formulated to provide appropriate administration to a patient for the treatment of pain without the undesirable known side effects.
14. The composition of claim 11, wherein the CR formulation further comprises TIMERx™-N and one chiral compound enantiomer such that a gum to drug ratio of between about 1:3 to 3:1, respectively, is established.
15. The composition of claim 11, wherein the CR formulation further comprises TIMERx™-O and one chiral compound enantiomer such that a gum to drug ratio of between about 1:3 to 3:1, respectively, is established.

16. The composition of claim 11, wherein about 90% of the (+) tramadol enantiomer and about 90% of the (-) tramadol enantiomer are released within about 12 hours of administration.

17. The composition of claim 11, wherein the (+) tramadol enantiomer and the (-) tramadol enantiomer are present in the composition at a percent ratio of 3:1, respectively.

18. The composition of claim 11, wherein the (+) tramadol enantiomer and the (-) tramadol enantiomer are present in the composition at a percent ratio of 2:1, respectively.

19. A pharmaceutical composition for oral delivery administration comprising tramadol, or a pharmaceutically acceptable salt thereof, wherein the tramadol, or a pharmaceutically acceptable salt thereof, is a combination of the two (+) and (-) tramadol enantiomers comprising (+) tramadol enantiomer, or a pharmaceutically acceptable salt thereof, in a controlled release (CR) formulation and the (-) tramadol enantiomer, or a pharmaceutically acceptable salt thereof, in an immediate release (IR) formulation for oral delivery administration, and wherein when administered to a patient, the pharmaceutical composition provides the following percent of maximum plasma concentrations for the (+) and (-) tramadol enantiomers:

Time (hours)	(+) Enantiomer	(-) Enantiomer
0	0%	0%
0.3	0-60 %	0-100 %
0.5	0-65 %	0-100 %
1.0	5-70 %	25-100 %
2.0	5-75 %	25-100 %
4.0	10-80 %	30-100 %
6.0	20-100 %	30-100 %
8.0	20-100 %	20-100 %
10.0	20-100 %	20-100 %
12.0	10-100 %	0-90 %
18.0	0-80 %	0-80 %
24.0	0-80 %	0-80 %

20. A pharmaceutical composition for oral delivery administration comprising tramadol, or a pharmaceutically acceptable salt thereof, wherein the tramadol, or a pharmaceutically acceptable salt thereof, is a combination of the two (+) and (-) tramadol enantiomers comprising (+) tramadol enantiomer, or a pharmaceutically acceptable salt thereof, in a controlled release (CR) formulation and the (-) tramadol enantiomer, or a pharmaceutically acceptable salt thereof, in an immediate release (IR) formulation for oral delivery administration, and wherein administered to a patient, the pharmaceutical composition provides the following percent of maximum plasma concentrations for the (+) and (-) tramadol enantiomers:



Time (hours)	(+) Enantiomer	(-) Enantiomer
0	0%	0%
0.3	0-40 %	0-100 %
0.5	0-45 %	0-100 %
1.0	5-50 %	25-100 %
2.0	5-55 %	25-100 %
4.0	10-80 %	30-100 %
6.0	20-100 %	30-100 %
8.0	20-100 %	20-100 %
10.0	10-100 %	20-100 %
12.0	0-80 %	10-90 %
18.0	0-80 %	0-80 %
24.0	0-80 %	0-80 %

- | Ingredients           | A        | (%)  |
|-----------------------|----------|------|
| 1. (+) Tramadol HCl   | 50 mg    | 5.4  |
| 2. TIMERx™-N          | 350 mg   | 37.7 |
| 3. Proslov            | 150 mg   | 16.2 |
| 4. Magnesium Stearate | 5.5 mg   | 0.6  |
| Total                 | 555.5 mg | 59.9 |

51

(b) an immediate release formulation consisting of about:

Ingredients	A	(%)
1. (-) Tramadol HCl	150 mg	16.2
2. Prosolv	100 mg	10.8
3. Lactose Fast-Flow	100 mg	10.8
4. Explotab	20 mg	2.2
5. Magnesium Stearate	3 mg	0.3
Total	373 mg	40.3

22. The pharmaceutical composition of claim 1 or claim 9 or claim 10 or claim 11 or claim 19 or claim 20, wherein the weight/weight percentage of TIMERx™-N in the formulation is 38%.

23. The pharmaceutical composition of claim 1 or claim 9 or claim 10 or claim 11 or claim 19 or claim 20, wherein the weight/weight percentage of TIMERx™-O in the formulation is 38%.

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a1